K050806

FEB 8 2006

Traditional 510(k) Summary of Safety and Effectiveness

This 510(k) Summary for OpteCure is provided as required per Section 513(1)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** Exactech Inc.
2320 NW 66th Court
Gainesville, Florida 32653
Telephone 352-377-1140
Fax 352-378-2617

Contact person: Maritza Elias
Regulatory Representative
Exactech Inc.
2320 NW 66th Court
Gainesville, Florida
Telephone 352-377-1140
Fax 352-378-2617

Date of original 510k submission: March 27, 2005
Date of follow-up information November 7, 2005

FDA Establishment Number 1038671

2. **Proprietary Name:** OpteCure
Common Name: Bone void filler
Product Code: MQV, MBP
Device Class: Class II
Classification Name: 21CFR §888.3045 Resorbable calcium salt bone void filler device
Classification Panel: Orthopaedic

Traditional 510(k) Summary of Safety and Effectiveness

3. Legally Marketed Devices for Substantial Equivalence Comparison:

Product Code	Manufacturer	510(k) Number	Product
MQV, MBP	Exactech Inc.	K040755	Exactech Resorbable Bone Paste
MQV	Regeneration Technologies Inc	K043420	Regenafil Allograft Paste, Regenafil RT Paste, Osteofil, Optefil, RTI Allograft Paste
MQV	Biomatlante	K043005	MBCP
MQV	Wright Medical Technologies	K020895	Allomatrix

4. Comparison to the Predicate Device(s):

OpteCure is the substantially equivalent to the predicate devices.

5. Device Description:

OpteCure comes in the form of a kit with pre-measured powder and demineralized bone matrix (DBM), pre-measured mixing solution and all the tools necessary to mix the components. After the powder is hydrated the resultant putty can then be handled and placed in the appropriate bone voids. Supplied as aseptic manufacture, single use, ready to mix implantable device derived from a single donor.

OpteCure gradually resorbs and is replaced with new bone during the healing process.

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6. Indications for Use

OpteCure is intended for use as a bone graft extender (extremities, spine and pelvis) and as a bone void filler (extremities and pelvis) for bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

OpteCure may be used with rigid fixation systems.

7. Safety & Effectiveness Information

a. Osteoinductive Potential

Samples from each lot of donor demineralized bone matrix (DBM) are formulated with the carrier and tested for osteoinductivity in an in-vivo athymic mouse assay. Findings from the animal model are not necessarily predictive of human clinical results.

b. Viral Inactivation Validation

A viral reduction study was conducted by a CLIA certified testing laboratory using four virus models representing RNA, DNA, envelope and non-envelope virus. This study demonstrates the demineralization process used on donor bone contained in OpteCure significantly diminishes these model viruses and can reasonably be anticipated to diminish the titers of other viruses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 8 2006

Ms. Maritza Elias
Regulatory Affairs Representative
Exactech Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K050806
OpteCure
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MBP, MQV
Dated: November 8, 2005
Received: November 10, 2005

Dear Ms. Elias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050806

Device Name: OpteCure

Indications for Use:

OpteCure is intended for use as a bone graft extender (extremities, spine and pelvis) and as a bone void filler (extremities and pelvis) for bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

OpteCure may be used with rigid fixation systems.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050806